

BEST AVAILABLE COPY

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11) Publication number:

0 428 253 B1

(12)

EUROPEAN PATENT SPECIFICATION

- (45) Date of publication of patent specification: **27.07.94** (51) Int. Cl.⁵: **A61L 17/00, A61B 17/06**
- (21) Application number: **90310197.0**
- (22) Date of filing: **18.09.90**

(54) **Method and apparatus for heat tipping sutures.**

(30) Priority: **14.11.89 US 436439**

(43) Date of publication of application:
22.05.91 Bulletin 91/21

(45) Publication of the grant of the patent:
27.07.94 Bulletin 94/30

(84) Designated Contracting States:
CH DE ES FR GB IT LI NL SE

(56) References cited:

FR-A- 1 478 695	FR-A- 2 361 119
US-A- 1 665 216	US-A- 3 422 181
US-A- 3 875 946	US-A- 3 926 194
US-A- 3 980 177	US-A- 4 832 025

(73) Proprietor: **United States Surgical Corporation**
150 Glover Avenue
Norwalk, Connecticut 06856(US)

(72) Inventor: **Chesterfield, Michael P.**
32 Bayne Street
Norwalk, CT 06851(US)
Inventor: **Malinowski, Stanley J.**
2 Alctar Lane
Ridgefield, CT 06877(US)
Inventor: **Proto, George R.**
31 Hillcrest Avenue
West Haven, CT 06516(US)

(74) Representative: **Marsh, Roy David et al**
Hoffmann Eitle & Partner
Patent- und Rechtsanwälte
Postfach 81 04 20
D-81904 München (DE)

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

EP 0 428 253 B1

Description

This invention relates to surgical sutures and in particular to a surgical suture with a treated end for insertion into a surgical needle, and a treatment method there for.

5 Surgeons often use needles with attached sutures in surgical operations. A typical suture-needle combination is shown in Fig. 1. Generally, such needle suture combinations comprise a non-eyed needle with a cylindrical hole in a barrel shaped rear end for receiving a suture, and a suture with a treated end which is received into the hole. Provided with a needle suture combination, operating room personnel need not waste time trying to thread an eyed needle with a suture. After using the needle-suture combination to
 10 close a wound the surgeon may detach the needle either by cutting the suture or by pulling on the needle with sufficient force to detach the needle from the suture.

In making suture needle combinations, whether the needles be eyed or non-eyed, it is generally necessary to treat the tip of the suture in some manner in order to make it easier to insert the tip into the barrel end of the needle. Braided or woven sutures especially have a tendency to "broom" or flare out at
 15 the ends. The purpose of the treatment is to stiffen the tip of the suture, as, for example, the end of a sewing thread is wetted and twisted so that it may be inserted into the eye of a sewing needle.

With regard to surgical sutures, this "tipping" process generally has been accomplished by coating and/or soaking the end of the suture with a solution of a resinous tipping solution. One such solution is Mariotte mixture, which comprises a solution of polyamide resin in isopropyl alcohol and water. Another
 20 such solution is Gould mixture, which comprises a solution of polyamide resin in methanol.

Generally a suture to be tipped is first placed under tension to reduce slack so that it may be maintained in a predetermined position on a drum or other suture holding device. Optionally, the tension may be such as to reduce the diameter of the suture. The suture is then dipped into the tipping solution and allowed to dry while under tension. The sutures are then warmed in a drying oven at about 107°C
 25 (225°F) for about 10 minutes to dry the sutures. After drying the sutures can be cut and released from tension. The process results in a tipped end on each side of a cut. In cases where tension has optionally been employed to reduce the suture diameter, release of said tension will allow the suture to expand to its original diameter except at the tipped end portion. This can facilitate insertion of the end into a needle. A method for making a needle suture combination wherein the suture end has been treated with resin
 30 solutions is described in U.S. Patent Nos. 3,980,177 and 3,890,975.

Although dipped sutures prepared in accordance with the above procedures have been used successfully, there are several drawbacks with the use of tipping solutions. The main problems are those of consistency and controllability. Non-uniform solvent evaporation, caused by variations in oven temperature and heating time, result in uneven diameter reduction and inconsistency of tipping. Furthermore, the dried
 35 residue of polymer left after evaporation can flake off or develop cracks.

A further drawback in these known procedures is that the suture is permanently altered. After the suture has been inserted into a needle there is no need for it to be stiffened. A limp suture will lay in the position in which the surgeon leaves it, whereas a stiff suture can interfere with the suturing operation. Nevertheless, a suture tipped by the prior art solutions will always have a portion containing the stiff residue of included
 40 polymer resin.

Heating of certain filaments is known in the art. A method for heat setting of stretch oriented polyglycolic acid filaments is disclosed in U.S. Patent No. 3,422,181. This patent discloses a method for improving the strength retention and absorption rate of a polyglycolic acid filament to be used in a suture by subjecting the filament to dry heat at a relative humidity of not greater than 20% and at a temperature of
 45 between 50°C and 190°C.

Another method which has been employed for treating sutures involves melt fusion, as described in U.S. Patent No. 4,832,025, issued to Coates. The suture is heated to a temperature at least high enough to "melt fuse" a portion of the outer filaments of the suture. Such temperature is typically about 260°C to 300°C (500°F to 572°F). The suture stiffens upon cooling. Surface melting of the outer filaments has the
 50 effect of holding the filaments together when the suture is cut. It also causes stiffening of the suture which facilitates insertion of the suture end into the drilled hole of a needle. However, the melt fusion of suture has significant drawbacks.

Firstly, the melt fusion of filaments weakens the suture, whose tensile strength is degraded in proportion to the extent of melt fusion.

55 Secondly, melt fusion causes an irreversible change in the filaments which results in permanent stiffening and permanent loss of tensile strength.

Thirdly, with the temperatures required for melt-fusion an inconveniently short heating cycle is required. For example, for a size 2/0 silicone coated polyester suture heated to between 260°C to 300°C in a 4 mm.

diameter heating tunnel, the heating time is no more than about 3 seconds. Short heating times allow for more inconsistency and variation in the results of the tipping process than longer heating times.

What is needed is a method for heat tipping sutures which facilitates reversible stiffening of the suture without loss of tensile strength.

5 A method is disclosed for heat tipping sutures which is fully reversible and which causes substantially no loss of tensile strength. Heat tipping cycle times associated with the method of the present invention are of such duration to bring about evenness and consistency of results. The heat tipping method provided herein comprises delimiting a portion of the suture to be heat tipped, and heating the delimited portion of the suture to a heat tipping temperature and maintaining said temperature for a period of time, the heat
10 tipping temperature being such as to cause the portion of the suture to be reversely stiffened upon cooling.

In a preferred form, a predetermined portion of the suture is selected. The selected portion is heated to a predetermined temperature sufficient to cause the portion to be reversibly stiffened when the heat is maintained for a predetermined period of time and the portion is then permitted to be cooled. In the preferred embodiment the invention contemplates permitting the delimited portion of the suture to cool
15 passively, i.e. by contact with the surrounding air. However, it is with the scope of the invention to permit the delimited portion of the suture to cool actively, i.e. by blowing cool air thereby.

The method can additionally comprise winding the suture around a drum wherein the drum has a longitudinal concave channel or depression for delimiting a portion of the suture to be heated and a means for selectively adjusting the effective circumference of the drum relative to the suture.

20 The means for adjusting the circumference of the drum comprises a bar mounted within a longitudinal notch in the surface of the drum, the bar being radially movable between a position in which said bar extends a relatively further distance beyond the circumferential surface of the drum, and a position in which said bar extends a lesser distance or not at all beyond the circumferential surface of the drum. The bar is preferably spring mounted within a notch in the drum and resiliently biased to the first extending position.

25 Before heating the suture, tension can be applied to the suture by said means for adjusting the circumference of the drum.

The preferred tipping temperature is from about 149 °C (300 °F) to about 160 °C (320 °F), and heating is preferably accomplished by blowing a current of heated air across the suture. Blowing a stream of relatively cool air across the undelimited portion of the suture prevents the undelimited portion from being heated.
30 The period of heating time optimally is determined in accordance with the diameter of the suture. The heat tipping method of the present invention can additionally comprise cutting the heated portion of the suture.

Also provided herein is an apparatus for heat tipping a suture, the apparatus comprising a cylindrical drum, means associated with said drum for delimiting a portion of the suture to be heat tipped, and means for heating the delimited portion of the suture to a heat tipping temperature. The means associated with
35 said drum for delimiting a portion of the suture to be heat tipped comprises a concave channel or groove which extends longitudinally parallel to the axis of the drum. The means for heating the delimited portion of the suture to a heat tipping temperature preferably comprises an elongated hot air outlet for blowing air at a heat tipping temperature across the delimited portions of the suture.

The apparatus can additionally comprise means for applying tension to the suture, a means for cutting
40 the heated portion of the suture to divide said portion into two heat tipped ends comprising a knife which is transversely movable across the heat tipped portion of the suture, and a means to prevent the non-delimited portion of the suture from being heat tipped comprising at least one row of cool air outlets for blowing relatively cool air across the non-delimited portion of the suture. The cylindrical drum optimally has a means for adjusting the drum circumference relative to suture which comprises a bar mounted within a
45 longitudinal notch in surface of the drum, and the bar being radially movable between a position in which the bar extends a relatively further distance beyond the circumferential surface of the drum, and position in which the bar extends a relatively lesser distance or not at all beyond the circumferential surface of said drum. The bar is resiliently mounted, optimally by means of a spring.

Reference will now be made, by way of example, to the accompanying drawings, in which:

50 Fig. 1 illustrates a prior art needle-suture combination with a non-eyed needle;

Fig. 1a illustrates a prior art needle-suture combination with an eyed needle;

Fig. 2 is a perspective view of suture wound around a heat tipping apparatus constructed according to the present invention;

Fig. 3 illustrates the heat tipping drum positioned for the heat tipping procedure;

55 Fig. 4 illustrates the cutting operation;

Figs. 5a and 5b are side views of a heat tipped suture with and without diameter reduction, respectively;

Fig. 6 is a perspective view of a combination of a needle and a heat tipped suture;

Figs. 7a and 7b are photomicrographs illustrating the non-heat tipped control portion of the surface of a braided suture at magnifications of 100 and 1000, respectively;

Figs. 8a and 8b are photomicrographs illustrating the surface portion of a braided suture which has been heat tipped in accordance with the present invention, at magnification of 100 and 1000, respectively; and

5 Figs. 9a and 9b are photomicrographs illustrating the cut end of a portion of a suture which has been heat tipped in accordance with the present invention, at magnifications of 75 and 1000, respectively.

Fig. 1 illustrates a typical needle-suture combination 10 of the prior art. Needle 11 has a barrel shaped end 15 with a cylindrical hole 12 for receiving the end of suture 13. Once the suture is inserted a crimp 14 is put into the barrel to retain the suture. A needle-suture combination and methods and instrumentation for
10 making such combination are disclosed in U.S. Patent No. 3,980,177.

Fig. 1a illustrates a prior art eyed needle and suture combination. Needle 11a contains eye 16 through which suture 13a is threaded.

The heat tipping method of the present invention produces a suture which is reversibly stiffened. The heat tipped suture is stiff enough to be inserted into the barrel or eye of a surgical needle without brooming, but simple manipulation, such as bending and unbending the suture for example by drawing the fingers
15 along the suture, will restore the flexibility and normal limpness of the suture as well as the original diameter if the diameter had been reduced by tensioning. This characteristic, i.e. reversible stiffening, is highly advantageous since there are no unwanted after effects from the tipping process such as residual stiffness or polymer residue, and it is not achieved by the prior art processes which fuse the surface filaments or
20 glue them together with polymer resins.

Referring to Figs. 2 and 3, a preferred method is disclosed for heat tipping sutures. The first step of the preferred heat tipping method of the present invention is to wind the suture around a cylindrical drum, preferably under tension so that there is no loose slack. Optionally, greater tension may be applied to reduce the suture diameter.

25 Suture 20 is wound around cylindrical drum 21. The drum is preferably constructed from metal, e.g., stainless steel, although other materials of construction, such as plastics, may be employed. The circumference of the drum may be chosen in accordance with the intended length of the individual sutures after cutting. Means for winding sutures under tension are conventional in the art.

Drum 21 has a concave channel or groove 22 which extends longitudinally along the surface of the drum 21 in an orientation parallel to the axis of the drum 21 and transverse to the orientation of the suture 20. The concave channel 22 provides a means for delimiting the portion or section of the suture to be heat tipped. As can be seen from Figs. 2 and 3, the sutures 20 are stretched transversely across the mouth of the concave channel 22. The delimited portion of the suture is exposed for heating. The undelimited portion is held in close contact with the cylindrical drum 21, which is preferably made of thermally conductive metal
30 and which therefore provides some protection of the non-delimited portion of suture 20 from heating by conducting heat away from said undelimited portion. Different widths of concave channel 22 will result in different lengths of tipped portions of the suture.

Drum 21 optionally comprises a means for varying the effective circumferential distance of drum relative to the suture. Changing the effective circumference of the drum provides a means for applying
40 tension to the suture or reducing tension.

Referring to Fig. 3, the circumference adjusting device is preferably an elongated member or bar 23 which is mounted within a longitudinally extending notch 24 in the surface of drum 21. The bar 23 is movable radially between a position wherein the bar extends a relatively further distance beyond the surface of the drum (thereby presenting an effectively larger drum circumference to the suture and increasing suture tension) and a position wherein the bar extends a relatively lesser distance, or not at all,
45 beyond the surface of the drum. In the last mentioned position, the bar presents an effectively smaller drum circumference to the suture and lessening suture tension.

After the suture has been wound around the drum as shown, the drum is positioned in a heat treating apparatus as diagrammed in Fig. 3. The drum 21 is mounted above an elongated heating outlet 31 supplied by a source of hot air 37 shown schematically in Fig. 3. Thus the portions of the sutures 20 to be heat tipped are arrayed in alignment over the heating outlet 31. On each side of the heating outlet 31 there is a parallel extending line of cool air outlets 32. Heat tipping is optimally accomplished by blowing hot air from outlet 31 across the sutures 20. For this reason, the depth of channel 22 should be sufficient to accommodate adequate flow of the heated air past the delimited portions of the suture.
50

A source of cool air 35 shown schematically in Fig. 3 communicates with cool air from outlets 32 to provide a wall of cool air which protects the remaining portions of the sutures from inadvertent heating. The heat tipping process is optimally accomplished by providing a flow of hot air at a heat tipping temperature, which is defined as that temperature which causes a suture to be reversibly stiffened upon cooling to
55

ambient or room temperature. Heat tipping is delimited by variables of temperature of air flow, duration of heating time, and suture diameter. A larger suture diameter requires a longer heating time, and a higher heating temperature requires a shorter heating time. The heat tipping temperature is at least high enough to cause some alteration in either the macroscopic structure or the molecular structure of the suture material, but it should not be so high as to cause melting or deterioration of the suture. The optimum heat tipping temperature range is from about 149°C (300°F) to about 160°C (320°F). Of the three parameters of heat tipping - temperature, time, and suture diameter - it is best to hold temperature constant. Heat tipping is optimally done at 149°C (300°F) to 160°C (320°F) for all suture diameters with an adjustment of heating time in accordance with suture diameter. Temperatures lower than about 146°C (295°F) produce no heat tipping, or require long periods of heating, whereas temperatures above about 165°C (330°F) may cause structural damage to the suture, or are associated with heating times which are too short to control easily.

Table I below sets forth a tabulation of heating times for various size sutures at the preferred heat tipping temperature of about 160°C (320°F). As can be seen from Table I, the heating times range from 12 to 16 seconds for size 5/0 sutures, to about 60 to 65 seconds for size 2 sutures. These heating times allow the heat to transfer through the suture evenly and without localized inconsistencies caused by hot spots.

TABLE I

Copolymer of Glycolide and Lactide Type Suture Heat Tipping Temperature = 160°C (320°F)	
Suture Size	Heating Time (seconds)
2	60 - 65
1	50 - 55
1/0	42 - 46
2/0	25 - 30
3/0	22 - 28
4/0	14 - 18
5/0	12 - 16

Referring to Figs. 4, 5a and 5b, after the heating is completed the suture (90% glycolide/10% lactide) is allowed to cool to ambient or room temperature and the diameter modifier 23 is depressed to reduce tension. A knife 51 is drawn laterally across the heat tipped portion of the sutures 20a thereby cutting them and creating two heat tipped ends, 20b and 20c, at each cut. In cases where the suture diameter has been reduced through tensioning, it should be noted that when the tension is released the suture will expand to its original diameter except at the heat tipped portion 20a, which retains the smaller diameter of the tensioned suture, as shown in Fig. 5a. When the suture has not been tensioned so as to reduce its diameter the heat tipping process of the present invention will nevertheless facilitate insertion of the tipped end into a needle by stiffening the end and by preventing brooming of the braided filaments, as illustrated in Fig. 5b.

The heat tipped portion 20a provided in accordance with the present invention is stiff and is easily insertable into the barrel end of a surgical needle. Braided sutures which are heat tipped will not "broom" or expand. The heat tipped portion may be restored to substantially its original flexibility and limpness by manipulating it. e.g. running it through one's fingers while bending and curling it.

Heat tipping according to the present invention may be performed on a variety of suture materials such as, but not limited to, polymers and copolymers of glycolide and lactide polydioxane, collagen, silk, nylon, dacron, cotton, linen, etc., preferably braided.

Fig. 6 illustrates a needle suture combination employing a suture prepared in accordance with the present invention. Needle 71 has a barrel end 71a into which heat tipped braided suture 72 is inserted. The suture is fixed by crimping or swaging the barrel end as illustrated.

Figs. 7a and 7b illustrate a control portion of a coated synthetic absorbable suture.

Figs. 8a and 8b show the same suture in the heat tipped region. As is apparent from a comparison of the control region and the heat tipped region, there is no evidence of fusing or melting of the filaments by the heat tipping process of the present invention.

Figs. 9a and 9b show the cut end of the heat tipped region of a suture. As can be seen from the photomicrographs the heat tipping process of the present invention effectively eliminates fraying or brooming at the cut end of the suture, thereby permitting insertion of the cut end into barrel end of a

surgical needle, but without permanently rigidifying the heat tipped region of the suture.

Claims

- 5 1. A method for heat tipping a surgical suture comprising:
 - a) delimiting a portion of the suture to be heat tipped;
 - b) heating said delimited portion of said suture to a heat tipping temperature and maintaining said temperature for a period of time, said heat tipping temperature being such as to cause said portion of said suture to be reversibly stiffened upon being permitted to cool.
- 10 2. A method according to claim 1 wherein said delimiting comprises winding said suture around a drum.
3. A method according to claim 2 further comprising applying tension to said suture before heating.
- 15 4. A method according to claim 2 or 3 wherein said tension is applied by means for adjusting the effective circumference of the drum.
5. A method according to any one of the preceding claims wherein said heat tipping temperature is from about 149 °C (300 °F) to about 160 °C (320 °F).
- 20 6. A method according to any one of the preceding claims wherein heating a portion of said suture comprises blowing a current of heated air across said suture.
7. A method according to any one of the preceding claims further comprising blowing a stream of relatively cool air across the non-delimited portion of said suture to prevent said non-delimited portion from being heated.
- 25 8. A method according to any one of the preceding claims wherein said period of time is determined in accordance with the diameter of said suture.
- 30 9. A method according to any one of the preceding claims additionally comprising cutting the heated portion of said suture.
10. Apparatus for heat tipping a suture which comprises:
 - 35 a) a cylindrical drum;
 - b) means associated with said drum for delimiting a portion of said suture to be heat tipped;
 - c) means for heating said delimited portion of said suture to a heat tipping temperature.
- 40 11. Apparatus as claimed in claim 10 wherein said means associated with said drum for delimiting a portion of the suture to be heat tipped comprises a concave channel extending longitudinally parallel to the axis of the drum.
12. Apparatus as claimed in claim 10 or 11 wherein the means for heating the delimited portion of the suture to a heat tipping temperature comprises hot air outlet means for blowing air at a heat tipping temperature across the delimited portions of the suture.
- 45 13. Apparatus as claimed in claim 10, 11 or 12 comprising means for applying tension to the suture.
14. Apparatus as claimed in any one of claims 10 to 13 further comprising means for cutting said heated portion of said suture so as to divide said portion into two heat tipped ends.
- 50 15. Apparatus as claimed in claim 14 wherein said means for cutting comprises a knife which is transversely movable across the heat tipped portion of the suture.
- 55 16. Apparatus as claimed in any one of claims 10 to 15 further comprising means to prevent said non-delimited portion of the suture from being heat tipped.

17. Apparatus as claimed in claim 16 wherein said means to prevent the non-delimited portion of the suture from being heat tipped comprises at least one row of cool air outlets for blowing relatively cool air across the non-delimited portion of the suture.
- 5 18. Apparatus as claimed in any one of claims 10 to 17 wherein said cylindrical drum has means for adjusting the drum circumference relative to suture.
19. Apparatus as claimed in claim 18 wherein said means for adjusting said drum circumference comprises an elongated member mounted within a longitudinal notch in surface of the drum, and said elongated member being radially movable between a first position whereby said elongated member extends a relatively further distance beyond the circumferential surface of the drum, and a second position whereby said elongated member extends a relatively lesser distance beyond the circumferential surface of said drum.
- 10 20. Apparatus as claimed in claim 19 wherein said second position of said elongated member does not extend beyond the circumferential surface of said drum.
- 15 21. A method for heat tipping a surgical suture comprising:
 - a) selecting a predetermined portion of the suture;
 - 20 b) heating said selected portion of said suture to a predetermined temperature sufficient to cause said portion of said suture to be reversibly stiffened when said heat is maintained for a predetermined period of time and said selected portion of said suture is permitted to cool;
 - c) maintaining said temperature for said predetermined period of time; and
 - 25 d) permitting said selected portion of said suture to be cooled.

Patentansprüche

1. Verfahren zum Wärme-Spitzenbehandeln eines chirurgischen Fadens, umfassend:
 - a) Abgrenzen eines Abschnittes des Fadens, der wärme-spitzenbehandelt werden soll;
 - 30 b) Erhitzen des abgegrenzten Abschnittes des Fadens auf eine Wärme-Spitzenbehandlungstemperatur und Aufrechterhalten der Temperatur für eine vorbestimmte Zeitdauer, wobei die Wärme-Spitzenbehandlungstemperatur derart ist, daß sie ein reversibles Versteifen des Abschnittes des Fadens bei Gestatten einer Abkühlung des Abschnittes des Fadens verursacht.
- 35 2. Verfahren nach Anspruch 1, worin das Abgrenzen ein Wickeln des Fadens um eine Trommel umfaßt.
3. Verfahren nach Anspruch 2, ferner umfassend Anlegen einer Spannung an den Faden vor dem Erhitzen.
- 40 4. Verfahren nach Anspruch 2 oder 3, worin die Spannung durch eine Einrichtung zum Einstellen des effektiven Umfangs der Trommel angelegt wird.
- 45 5. Verfahren nach einem beliebigen der vorgenannten Ansprüche, worin die Wärme-Spitzenbehandlungstemperatur von etwa 149°C (300°F) bis etwa 160°C (320°F) reicht.
- 50 6. Verfahren nach einem beliebigen der vorangegangenen Ansprüche, worin das Erhitzen eines Abschnittes des Fadens das Blasen einer Strömung erhitzter Luft über den Faden umfaßt.
7. Verfahren nach einem beliebigen der vorangegangenen Ansprüche, ferner umfassend das Blasen einer Strömung relativ kühler Luft über den nicht abgegrenzten Abschnitt des Fadens, um ein Erwärmen des nicht abgegrenzten Abschnittes zu vermeiden.
- 55 8. Verfahren nach einem beliebigen der vorangegangenen Ansprüche, worin die Zeitdauer entsprechend dem Durchmesser des Fadens bestimmt wird.

9. Verfahren nach einem beliebigen der vorangegangenen Ansprüche, zusätzlich umfassend das Schneiden des erhitzten Abschnitts des Fadens.
10. Vorrichtung zum Wärme-Spitzenbehandeln eines Fadens, umfassend:
 - 5 a) eine zylindrische Trommel;
 - b) eine der Trommel zugehörige Einrichtung zum Abgrenzen eines Abschnittes des Fadens, der wärme-spitzenbehandelt werden soll;
 - c) eine Einrichtung zum Erhitzen des abgegrenzten Abschnittes des Fadens auf eine Wärme-Spitzenbehandlungstemperatur.
- 10 11. Vorrichtung nach Anspruch 10, worin die der Trommel zugehörige Einrichtung zum Abgrenzen eines Abschnittes des Fadens, der wärme-spitzenbehandelt werden soll, eine konkave Nut umfaßt, die sich longitudinal parallel zu der Achse der Trommel erstreckt.
- 15 12. Vorrichtung nach Anspruch 10 oder 11, worin die Einrichtung zum Erhitzen des abgegrenzten Abschnittes des Fadens auf eine Wärme-Spitzenbehandlungstemperatur eine Heißluftauslaßeinrichtung zum Blasen von Luft bei einer Wärme-Spitzenbehandlungstemperatur über den abgegrenzten Abschnitt des Fadens umfaßt.
- 20 13. Vorrichtung nach Anspruch 10, 11 oder 12, umfassend eine Einrichtung zum Anlegen einer Spannung an den Faden.
- 25 14. Vorrichtung nach einem beliebigen der Ansprüche 10 bis 13, ferner umfassend eine Einrichtung zum Schneiden des erhitzten Abschnittes des Fadens, um den Abschnitt in zwei wärme-spitzenbehandelte Enden zu teilen.
- 30 15. Vorrichtung nach Anspruch 14, worin die Schneideinrichtung ein Messer umfaßt, das quer über den wärme-spitzenbehandelten Abschnitt des Fadens beweglich ist.
- 35 16. Vorrichtung nach einem beliebigen der Ansprüche 10 bis 15, ferner umfassend eine Einrichtung zum Verhindern des Wärme-Spitzenbehandelns des nicht abgegrenzten Abschnittes des Fadens.
- 40 17. Vorrichtung nach Anspruch 16, worin die Einrichtung zum Verhindern des Wärme-Spitzenbehandelns des nicht abgegrenzten Abschnittes des Fadens mindestens eine Reihe Kühlluftauslässe zum Blasen relativ Luft über den nicht abgegrenzten Abschnitt des Fadens umfaßt.
- 45 18. Vorrichtung nach einem beliebigen der Ansprüche 10 bis 17, worin die zylindrische Trommel eine Einrichtung zum Einstellen des Trommelumfangs relativ zum Faden besitzt.
- 50 19. Vorrichtung nach Anspruch 18, worin die Einrichtung zum Einstellen des Trommelumfangs ein innerhalb einer Längsnut in der Oberfläche der Trommel angebrachtes langgestrecktes Bauteil umfaßt, und das langgestreckte Bauteil radial beweglich ist zwischen einer ersten Position, bei der sich das langgestreckte Bauteil eine relativ weite Distanz über die Umfangsfläche der Trommel erstreckt, und einer zweiten Position, bei der sich das langgestreckte Bauteil eine relativ geringere Distanz über die Umfangsfläche der Trommel erstreckt.
- 55 20. Vorrichtung nach Anspruch 19, worin sich die zweite Position des langgestreckten Bauteils nicht über die Umfangsfläche der Trommel erstreckt.
21. Verfahren zum Wärme-Spitzenbehandeln eines chirurgischen Fadens, umfassend:
 - a) Auswählen eines vorbestimmten Abschnittes des Fadens;

- b) Erhitzen des ausgewählten Abschnittes auf eine vorbestimmte Temperatur, die hinreichend ist, um ein reversibles Versteifen des Abschnittes des Fadens zu verursachen, wenn die Hitze eine vorbestimmte Zeitdauer aufrechterhalten und dem ausgewählten Abschnitt des Fadens gestattet wird abzukühlen;
- 5 c) Aufrechterhalten der Temperatur für die vorbestimmte Zeitdauer; und
- d) Ermöglichen einer Abkühlung des ausgewählten Abschnittes des Fadens.

Revendications

- 10 1. Procédé pour exécuter un traitement thermique d'extrémité d'un fil de suture chirurgical comprenant les étapes consistant à :
 - a) délimiter une portion du fil de suture à soumettre au traitement thermique d'extrémité ;
 - b) chauffer ladite portion délimitée dudit fil de suture à une température de traitement thermique d'extrémité et à maintenir ladite température pendant une période de temps, ladite température de traitement thermique d'extrémité étant choisie de façon à provoquer que ladite portion dudit fil de suture soit rendue rigide de manière réversible après son refroidissement.
- 15 2. Procédé selon la revendication 1, dans lequel ladite délimitation comprend l'enroulement dudit fil de suture autour d'un tambour.
- 20 3. Procédé selon la revendication 2, comprenant en outre l'application d'une tension audit fil de suture avant l'échauffement.
- 25 4. Procédé selon la revendication 2 ou 3, dans lequel ladite tension est appliquée par un moyen prévu pour régler la circonférence effective du tambour.
- 5. Procédé selon l'une des revendications précédentes, dans lequel ladite température de traitement thermique d'extrémité s'étend d'environ 149 °C (300 °F) à environ 160 °C (320 °F).
- 30 6. Procédé selon l'une des revendications précédentes, dans lequel l'échauffement d'une portion dudit fil de suture comprend le soufflage d'un courant d'air chauffé sur ledit fil de suture.
- 35 7. Procédé selon l'une des revendications précédentes, comprenant en outre le soufflage d'un flux d'air relativement froid sur la portion non délimitée dudit fil de suture pour empêcher que ladite portion non délimitée soit chauffée.
- 8. Procédé selon l'une des revendications précédentes, dans lequel ladite période de temps est déterminée en accord avec le diamètre dudit fil de suture.
- 40 9. Procédé selon l'une des revendications précédentes, comprenant additionnellement la coupe de ladite portion chauffée dudit fil de suture.
- 10. Appareil pour effectuer un traitement thermique d'extrémité d'un fil de suture qui comprend :
 - a) un tambour cylindrique ;
 - 45 b) un moyen associé audit tambour pour délimiter une portion dudit fil de suture à soumettre au traitement thermique d'extrémité ;
 - c) un moyen pour chauffer ladite portion délimitée dudit fil de suture à une température de traitement thermique d'extrémité.
- 50 11. Appareil selon la revendication 10, dans lequel ledit moyen associé audit tambour pour délimiter une partie du fil de suture à soumettre au traitement thermique d'extrémité comprend un canal concave s'étendant longitudinalement parallèlement à l'axe du tambour.
- 55 12. Appareil selon la revendication 10 ou 11, dans lequel le moyen pour chauffer la portion délimitée du fil de suture à une température de traitement thermique d'extrémité comprend un moyen de sortie d'air chaud pour souffler de l'air à une température de traitement thermique d'extrémité sur les portions délimitées du fil de suture.

13. Appareil selon la revendication 10, 11 ou 12, comprenant un moyen pour appliquer une tension au fil de suture.
- 5 14. Appareil selon l'une des revendications 10 à 13, comprenant en outre un moyen pour couper ladite portion chauffée dudit fil de suture de façon à diviser ladite portion en deux extrémités ayant subi le traitement thermique d'extrémité.
- 10 15. Appareil selon la revendication 14, dans lequel ledit moyen de coupe comprend un couteau qui est déplaçable transversalement sur la portion ayant subi le traitement thermique d'extrémité du fil de suture.
16. Appareil selon l'une des revendications 10 à 15, comprenant en outre un moyen pour empêcher que ladite portion non délimitée du fil de suture soit soumise au traitement thermique d'extrémité.
- 15 17. Appareil selon la revendication 16, dans lequel ledit moyen pour empêcher que la portion non délimitée du fil de suture soit soumise au traitement thermique d'extrémité comprend au moins une rangée de sorties d'air de refroidissement pour souffler de l'air relativement froid sur la portion non délimitée du fil de suture.
- 20 18. Appareil selon l'une des revendications 10 à 17, dans lequel ledit tambour cylindrique présente un moyen pour régler la circonférence du tambour relativement au fil de suture.
- 25 19. Appareil selon la revendication 18, dans lequel ledit moyen pour régler ladite circonférence de tambour comprend un élément allongé monté à l'intérieur d'une encoche longitudinale dans la surface du tambour et ledit élément allongé étant déplaçable radialement entre une première position dans laquelle ledit élément allongé s'étend sur une distance relativement importante au-delà de la surface circonférentielle du tambour, et une deuxième position dans laquelle ledit élément allongé s'étend sur une distance relativement plus courte au-delà de la surface circonférentielle dudit tambour.
- 30 20. Appareil selon la revendication 19, dans lequel ledit élément allongé, lorsqu'il se trouve dans ladite deuxième position, ne s'étend pas au-delà de la surface circonférentielle dudit tambour.
- 35 21. Procédé pour effectuer un traitement thermique d'extrémité d'un fil de suture chirurgical comprenant les étapes consistant à :
 - a) choisir une portion prédéterminée du fil de suture ;
 - b) chauffer ladite portion choisie dudit fil de suture à une température prédéterminée suffisamment élevée pour provoquer que ladite portion dudit fil de suture soit rendue rigide de manière réversible lorsque ladite chaleur est maintenue pendant une période de temps prédéterminée et qu'on a laissé refroidir ladite portion choisie dudit fil de suture ;
 - 40 c) maintenir ladite température pendant ladite période de temps prédéterminée ; et
 - d) laisser refroidir ladite portion choisie dudit fil de suture.

45

50

55

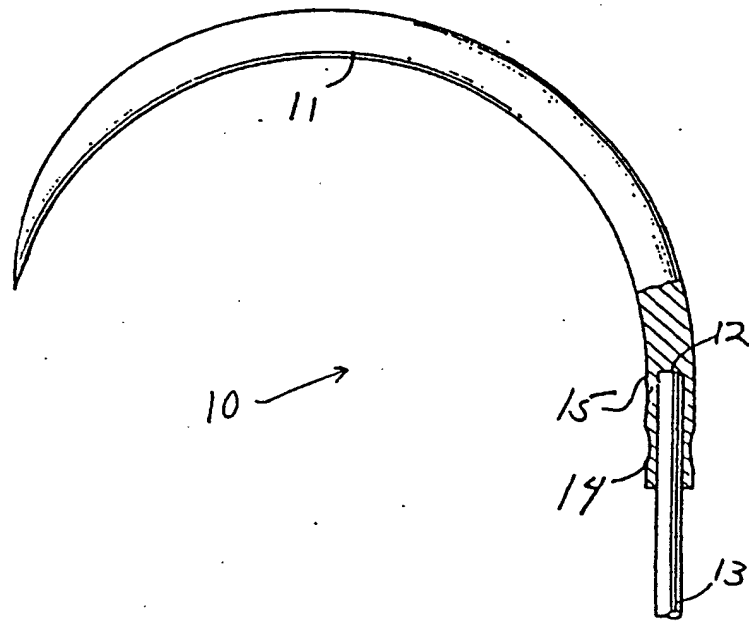


Fig 1
PRIOR ART

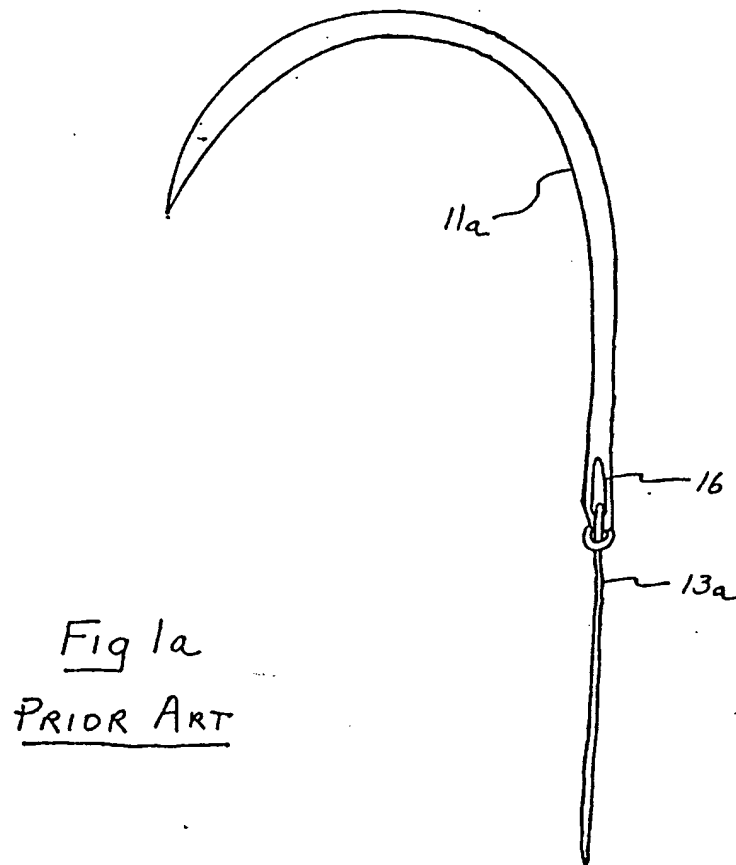


Fig 1a
PRIOR ART

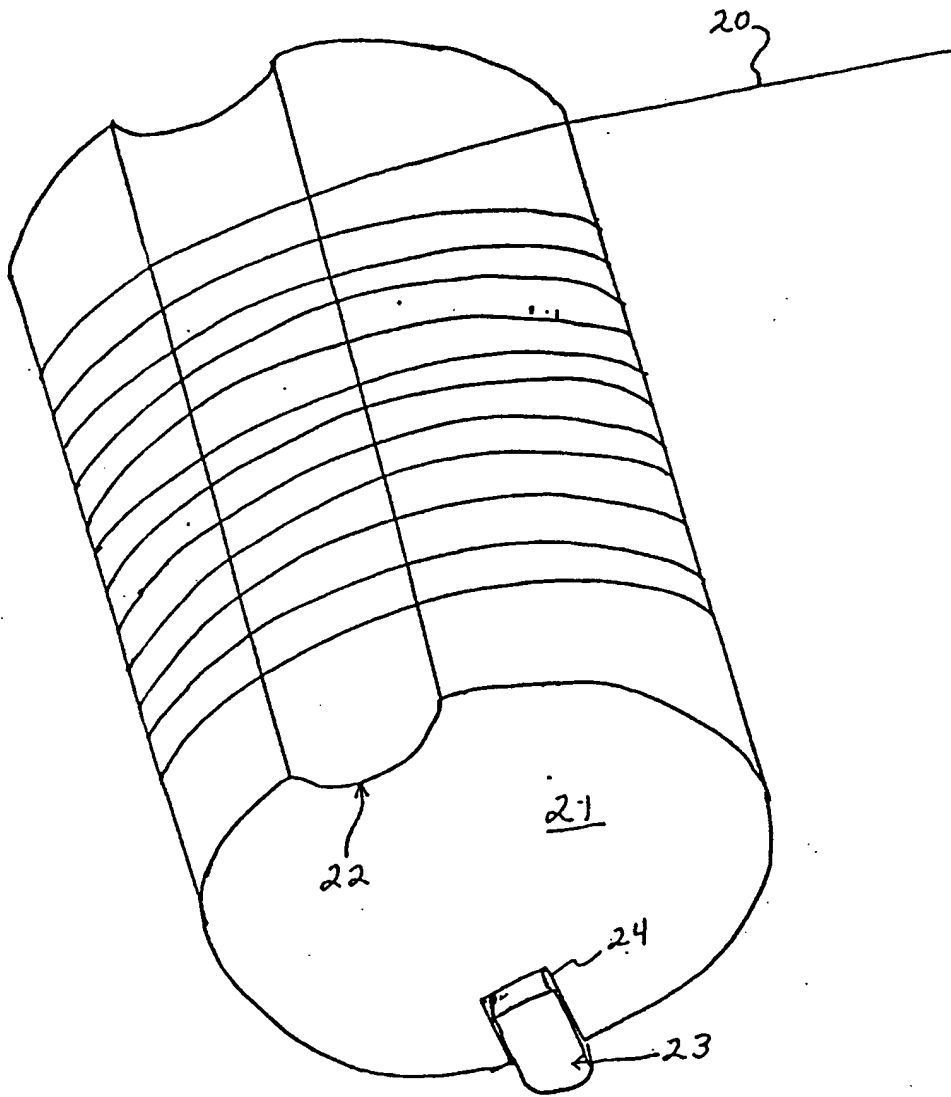


Fig 2

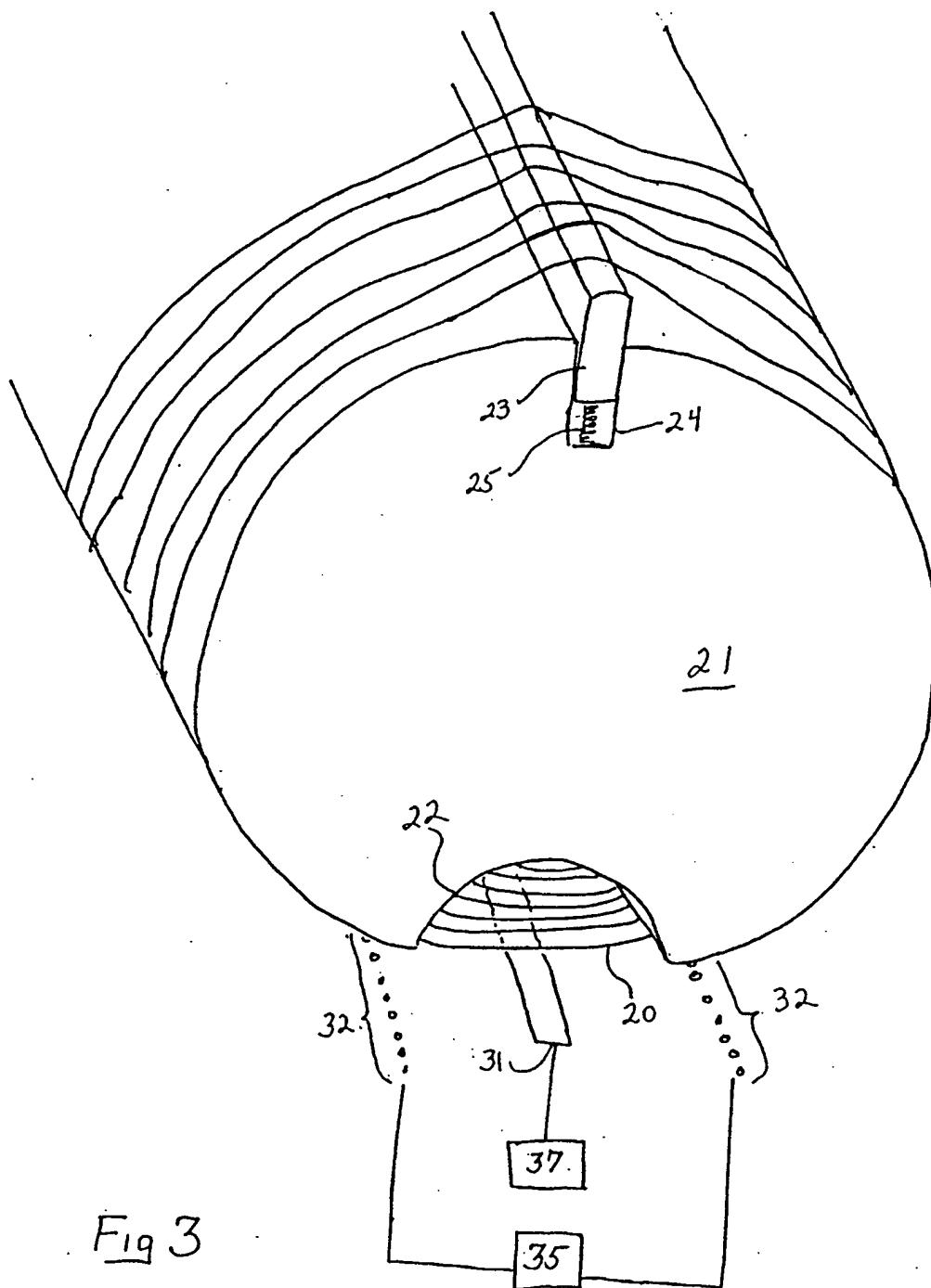


Fig 4

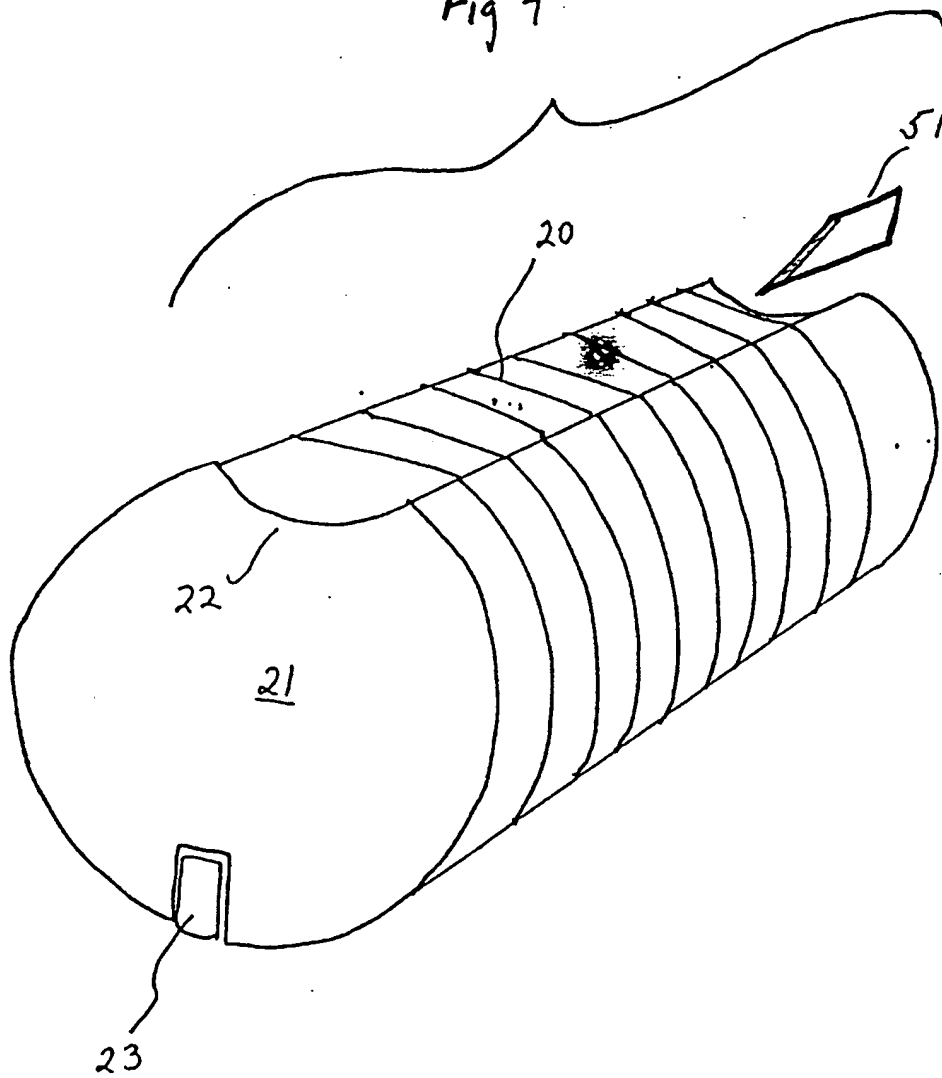


Fig 5a

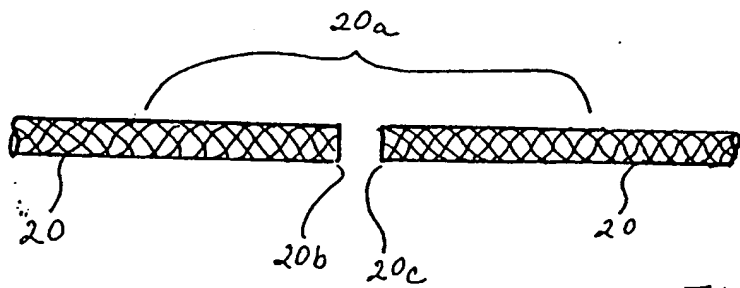
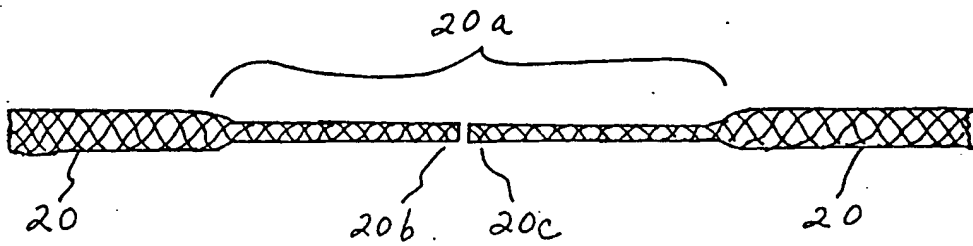
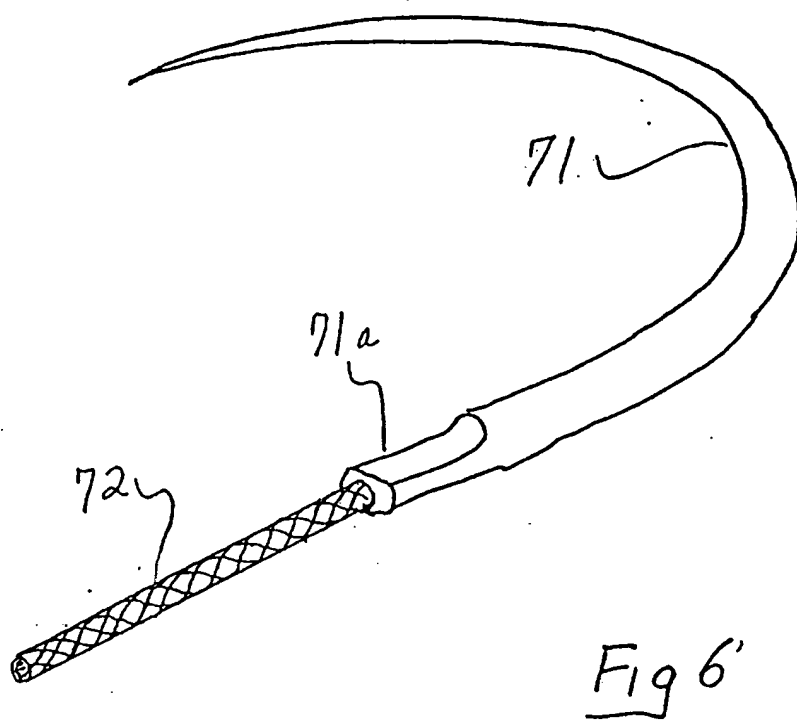


Fig 5b



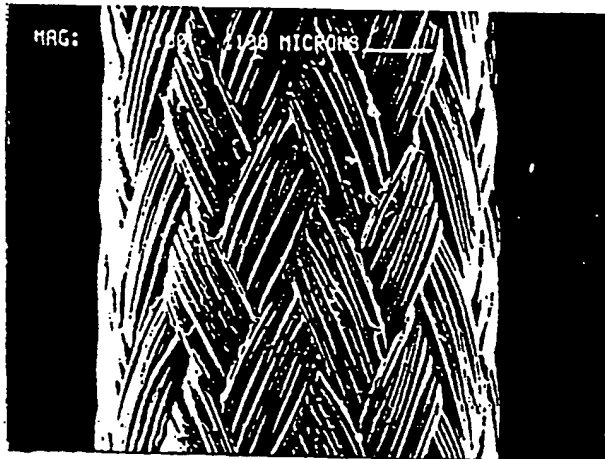


FIG. 7a

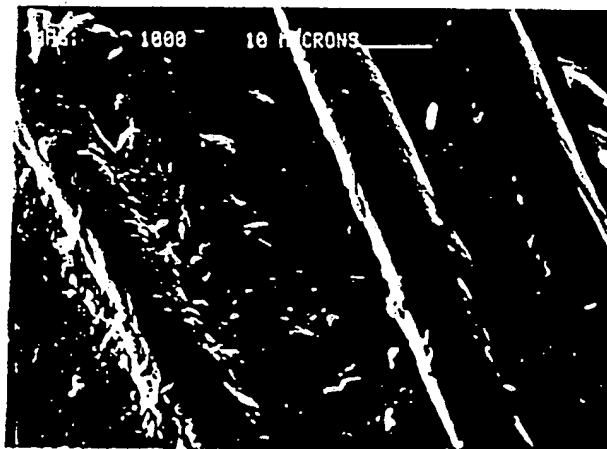


FIG. 7b

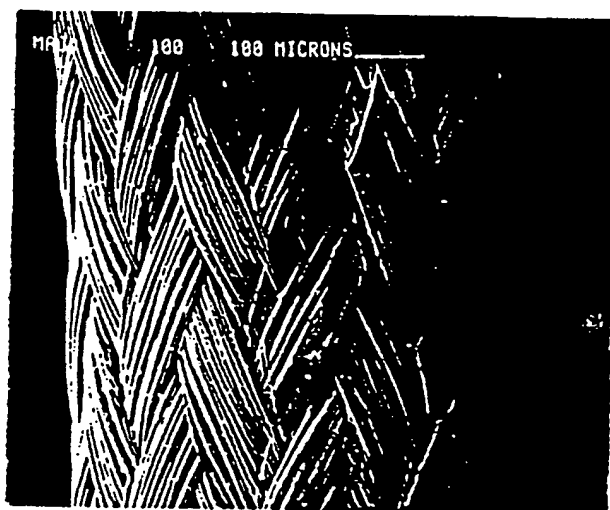


FIG. 8a

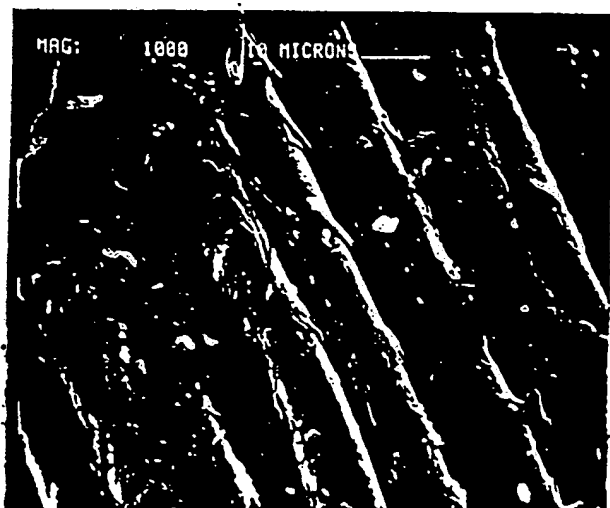


FIG. 8b

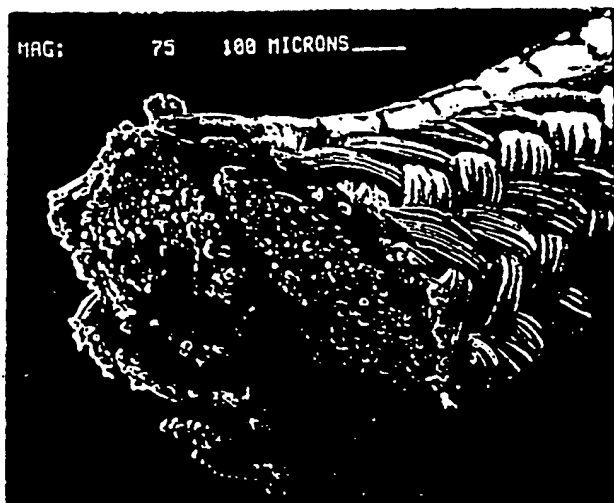


FIG. 9a



FIG. 9b

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.